IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

KEYSOURCE MEDICAL, INC.,	:	Case No. 1:11-cv-393
	:	
Plaintiff,	:	Chief Judge Susan J. Dlott
	:	
v.	:	ORDER DENYING PLAINTIFF'S
	:	MOTION FOR TEMPORARY
ERIC HOLDER, JR.,	:	RESTRAINING ORDER AND FOR
Attorney General of the United States, et al.,	:	PRELIMINARY INJUNCTION
	:	
Defendants.	:	

This matter comes before the Court on Plaintiff's motion for a temporary restraining order and motion for a preliminary injunction. (*See* doc. 2.) In filing the instant action, Plaintiff sought to enjoin an immediate suspension order issued by the Drug Enforcement Administration ("DEA") on June 9, 2011. On June 17, 2011, the Court modified that suspension until such time that a hearing could be held on the issuance of a preliminary injunction. (Doc. 6.) The Court held a preliminary injunction hearing on July 5 and 6, 2011 during which the Court heard testimony from seven witnesses. After considering this testimony as well as the exhibits, arguments, and other materials submitted by counsel, the Court denied the Plaintiff's motion in a ruling from the bench for the reasons set forth below.

I. BACKGROUND

A. Controlled Substances Act

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. §§ 801-971 (1988) (& Supp. IV 1992) (the Controlled Substances Act or "CSA"), based on a finding that "the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and

general welfare of the American people." 21 U.S.C. § 801(2). "A 'main objective' of the [CSA] is controlling 'illegitimate traffic in controlled substances,' by placing 'substances in one of five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision.'" *Volkman v. U.S. Drug Enforcement Admin.*, 567 F.3d 215, 221 (6th Cir. 2009) (quoting *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006)).

The CSA authorizes the DEA to regulate the distribution of controlled substances with the goal of creating a closed-system of distribution. (*See* Decl. of Joseph Rannazzisi (Doc. 9-1) ¶¶ 5-6; Testimony of Kyle Wright (July 6, 2011).) The CSA also authorizes the DEA to establish a registration program for handlers of controlled substances in order to prevent the diversion of legally-produced controlled substances into the illicit market. 21 U.S.C. §§ 821, 822. In turn, the DEA is authorized to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. The CSA imposes criminal, civil, and administrative penalties for the illegal distribution of controlled substances and for failure of DEA registrants to maintain the requisite controls to prevent diversion. *See, e.g.*, 21 U.S.C. §§ 841, 842, 843, 824.

Any entity that wishes to handle controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11. Registrants are subject to a variety of recordkeeping, reporting, and security requirements relating to controlled substances. *See* 21 U.S.C. § 827 (inventory reporting requirements), § 825 (labeling and packaging requirements), §§828, 829 (order forms, prescriptions); 21 C.F.R. §§ 1302-1307. Specifically, distributors are required to

"design and operate a system to disclose to the registrant suspicious orders of controlled substances" and, in turn, to disclose those suspicious orders to the DEA. 21 C.F.R. § 1301.74(b) (defining "suspicious orders" to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.").

The DEA has authority to revoke or suspend a party's registration for a variety of reasons, including that a registrant "has committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). One factor in determining if a distributor has failed to act in the public interest is the "maintenance of effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1), (e)(1). Prior to suspending or revoking a party's registration, the DEA must issue an order to show cause describing the basis for initiating proceedings and also allowing for an administrative hearing. 21 U.S.C. § 824(c).

Federal law also authorizes the DEA to act more quickly when it has reason to believe that a party's continued registration poses "an imminent danger to the public health or safety." 21 U.S.C. § 824(d). In such cases, the DEA has the discretion to suspend that party's registration immediately, after which an administrative hearing will be held. 21 C.F.R. § 1301.42. After receiving an order to show cause, a registrant can request an expedited hearing, which the DEA is required to grant "as early as reasonably possible." 21 C.F.R. § 1301.36(h). A suspension remains in effect until the DEA issues a final order, unless the suspension is withdrawn by the Attorney General or is dissolved by a court of competent jurisdiction. 21 U.S.C. § 824(d).

B. KeySource Medical

KeySource Medical, Inc. ("KMI") is a secondary wholesaler of generic pharmaceutical drugs, including controlled substances that are regulated by the DEA. KMI sells both controlled and non-controlled substances and over-the-counter products to independent retail pharmacies as well as a mix of small chain, long-term care, hospice, and specialty pharmacies in forty-seven states. (Testimony of Dennis J. Engel (July 5, 2011); Decl. of Dennis J. Engel (Doc. 2-3) ¶ 2.) Founded in 1996, KMI has one distribution facility at its Cincinnati, Ohio location. (*Id.* ¶¶ 2-3.)

Between 2008 and 2011, KMI increased its purchases of hydrocodone and oxycodone, two drugs commonly associated with abuse and diversion. (Wright Testimony; Decl. of Kyle Wright (Doc. 9-3) ¶ 10; DX 1007 at 7-8.) According to a database maintained by the DEA,[1] KMI doubled the amount of hydrocodone it purchased in 2008 and doubled it again in 2009, when it purchased and distributed 28.6 million units of the drug. (Wright Decl. ¶ 11; Def. Ex. 1007 at 7.) KMI also increased its purchases of oxycodone, which more than doubled in 2008 (to 2.4 million dosage units), increased fivefold in 2009 (to 16.2 million dosage units), and tripled in 2010 (to 50.9 million dosage units). (Wright Decl. ¶ 12; Def. Ex. 1007 at 8.) In terms of drug strength, most of KMI's controlled substances sales that were reported to the DEA were of two particular drugs – oxycodone 30 mg and hydrocodone 10 mg – that have a high street value and pose a substantial risk of diversion. (Wright Decl. ¶¶ 15-17; Def. Ex. 1007 at 10-11.)

KMI's sales of oxycodone to the state of Florida are particularly significant, for reasons that are explained in the next section. Beginning in or around 2009, KMI began distributing

[1] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. (Wright Decl. ¶ 2.) Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. (Engel Testimony.)

pharmaceutical drugs to Florida. (Am. Decl. of David Hoffman, R.Ph (Doc. 5) ¶ 12.) Between January 1, 2009 and May 31, 2011, KMI sold 52,880,400 dosage units of oxycodone, a powerful and addictive narcotic that is regulated as a schedule II controlled substance based on its high potential for abuse and addiction. (Wright Testimony; Wright Decl. ¶ 5; Def. Ex. 1007 at 3.) In 2010 alone, KMI sold 41,502,500 dosage units of oxycodone to pharmacies in Florida. (Wright Decl. ¶ 19; Def. Ex. 1007 at 4.) Among similarly situated distributors – i.e., those with only one distribution facility – KMI was the top supplier of oxycodone to Florida in 2010 and the first three months of 2011. (Wright Decl. ¶¶ 21-23; Def. Ex. 1007 at 30-33.)

C. Prescription Drug Epidemic in Florida

During this same period, an epidemic of prescription drug abuse was already underway in Florida. As explained in the testimony of Susan Langston, a DEA Diversion Group Supervisor located in southern Florida, this epidemic is the result of the actions of numerous individuals: those – including criminal trafficking organizations – who seek drugs for purposes that range from addiction to profit; physicians in "pill mills" who prescribe oxycodone without legitimate medical purposes; pharmacists who willingly fill these illegitimate prescriptions; and distributors who supply pharmacies with the drugs necessary to fill these prescriptions.

The devastation caused by this problem is well-known in the pharmaceutical industry and, in fact, the general public. (Testimony of Susan Langston (July 6, 2011).) The number of overdose deaths associated with oxycodone in Florida has been increasing between 2005 and 2010. (Rannazzisi Decl. ¶ 10 (summarizing data from Florida Medical Examiner's Office).) The impact of diversion also extends beyond Florida into states like Ohio and Kentucky. In these states – and many others – drug trafficking organizations "sponsor" individuals to travel to

Florida, obtain prescriptions for drugs like oxycodone and hydrocodone, and bring them back into their local communities – creating what many investigators refer to as the "Florida Pipeline" or the "Oxycontin Express." (Langston Testimony; Decl. of Christopher Kresnak (Doc 9-2) ¶¶ 3-4.) The DEA estimates that, nationwide, over seven million Americans abuse prescription drug medications for illegal purposes. (Rannazzisi Decl. ¶ 7.)

D. DEA Investigation

The DEA began an investigation of KMI in December 2010. (Testimony of Michelle Cooper (July 6, 2011); Decl. of Michelle Cooper (Doc. 9-5) ¶ 4.) This investigation involved a review of purchasing data showing KMI's sales of oxycodone into Florida (*see* Def. Ex. 1007), correspondence from one of KMI's suppliers raising concerns that KMI was "selling what appears to be an unusually large amount of Oxycodone 15 mg and 30 mg into the State of Florida" (Def. Ex. 1004), and customer information relating to several pharmacies obtaining oxycodone from KMI (*see* Def. Ex. 1042 at 3-5).

On February 9, 2011, the DEA executed an Administrative Inspection Warrant on KMI in order to obtain customer files and other information relating to KMI's practices. (Def. Ex. 1042.) As explained by the testimony of the lead Diversion Investigator Michelle Cooper, the DEA also interviewed several KMI employees on the day that the search warrant was executed.

Based on its review of this information, the DEA Administrator issued an Order to Show Cause Immediate Suspension of Registration on June 9, 2011. (*See* Def. Ex. 1041 ("DEA Order").) The immediate suspension reflected the DEA's conclusion that allowing KMI to continue distributing controlled substances posed an imminent danger to the public health and

safety. (*Id.* at 1.) The Order set forth at least two reasons for the immediate suspension.[2] First, the DEA determined that KMI failed to detect suspicious orders and repeatedly filled suspicious orders without notifying the DEA. (DEA Order ¶¶ 2-3.) Second, the DEA found that KMI frequently received and filled orders from customers who ordered dosage units of the same oxycodone product using multiple lines of the same form. (Cooper Decl. ¶ 7.) The DEA also had concerns that KMI's top management discussed encouraging customers to increase orders of non-controlled substances so that KMI could supply them with more controlled substances. (*Id.* ¶¶ 8, 10; *see also* Def. Exs. 1009, 1011, 1013.)

E. Procedural History

The DEA Order provided KMI with the right to a hearing in front of an Administrative Law Judge ("ALJ") on August 9, 2011, during which KMI could show why it should be able to maintain its registration and resume the distribution of controlled substances. KMI requested a hearing on the Order to Show Cause but did not request to expedite this hearing. Instead, KMI filed suit in this court on June 15, 2011 challenging the immediate suspension order and alleging that the DEA had violated the Administrative Procedures Act ("APA"), the CSA, and the Fifth Amendment. (Doc. 1.) On the same date, the Plaintiff filed a motion seeking a temporary restraining order against the DEA. (Doc. 2.)

After two informal preliminary telephone conferences, the parties reached an agreement for a temporary resolution pending a hearing on the preliminary injunction, and the Court modified the DEA Order. (Doc. 6.) This order prohibited KMI from selling oxycodone in pill

[2] The Plaintiff argues that the Government's defense of Plaintiff's motion for a preliminary injunction should be limited to the information set forth in the DEA Order. (*See* Doc. 12.) The Court rejects this argument, finding that the DEA is entitled to respond to arguments raised by KMI regarding its suspicious order monitoring system.

form, but allowed KMI to sell oxycodone in liquid form and other Schedule II, III, IV, and V drugs, until the matter could be set for a hearing. (*Id.*)

The hearing was held on July 5 and July 6, 2011. The Court heard and considered testimony from the following KMI employees called by the Plaintiff as witnesses: Dennis Engel, Chief Executive Officer; David Hoffman, R.Ph., Compliance Officer; Robert Barnes, Compliance Coordinator; and Todd Szewc, Chief Financial Officer and Chief Information Officer. The Court also heard and considered testimony from the following DEA employees called by the Defendants as witnesses: Kyle Wright, Chief of the Targeting & Analysis Unit in the Office of Diversion Control; Michelle Cooper, Diversion Investigator in the Detroit Field Division Office; and Susan Langston, Diversion Group Supervisor in the Fort Lauderdale Field Diversion Office. The Court also considered declarations submitted with the briefs, exhibits introduced and admitted into evidence, and arguments from counsel.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 65 authorizes the Court to grant preliminary injunction relief. However, a preliminary injunction "'is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion.'" *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (quoting 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948, at 129-130 (2d ed.1995)) (emphasis added in *Mazurek*); *see also American Civil Liberties Union of Kentucky v. McCreary Co., Kentucky*, 354 F.3d 438, 444 (6th Cir. 2003) (stating that "[a] preliminary injunction is an extraordinary measure that has been characterized as 'one of the most drastic tools in the arsenal of judicial remedies.'" (quoting *Hanson Trust PLC v. ML SCM Acquisition Inc.*, 781 F.2d 264,

273 (2d Cir. 1986))). "'In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.'" *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 24 (2008) (quoting *Weinberger v. Romero–Barcelo*, 456 U.S. 305, 312 (1982)).

When deciding whether to grant preliminary injunctive relief, the Court considers four factors: (1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would otherwise suffer irreparable injury; (3) whether issuance of preliminary injunctive relief would cause substantial harm to others; and (4) whether the public interest would be served by issuance of preliminary injunctive relief. *See Leary v. Daeschner*, 228 F.3d 729, 736 (6th Cir. 2000); *see also Mason County Medical Ass'n v. Knebel*, 563 F.2d 256, 261 (6th Cir. 1977). "[T]he four considerations applicable to preliminary injunctions are factors to be balanced and not prerequisites that must be satisfied. . . . These factors simply guide the discretion of the court; they are not meant to be rigid and unbending requirements." *In re Eagle-Pitcher Industries, Inc.*, 963 F.2d 855, 859 (6th Cir. 1992) (citations omitted).

III. ANALYSIS

After considering all of the evidence presented in this case, the Court found for the reasons stated below that there were not sufficient grounds to grant the requested injunctive relief.

A. Substantial Likelihood of Success on the Merits

KMI faces two significant hurdles at the outset of this inquiry. First, the CSA provides the DEA with the authority to revoke or suspend a party's registration if it "has committed such acts as would render [its] registration . . . inconsistent with the public interest." 21 U.S.C. §

824(a)(4). One factor in making such a determination is the "maintenance of effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1), (e)(1). The CSA also authorizes the DEA with the authority to immediately suspend a registration that it finds poses "an imminent danger to the public health or safety." 21 U.S.C. § 824(d). In other words, "the CSA explicitly provides the Attorney General with *discretion* in deciding whether to issue a suspension order." *Neil Labs., Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 87 (D.D.C. 2002) (emphasis in original).

Second, the APA places a high burden on an entity challenging an administrative action. To succeed in such a challenge here, KMI must show that the DEA's action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The standard of review is highly deferential, and "[t]he court is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Instead, the court must apply a "presumption of regularity" and "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* A decision is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Veh. Mfgrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

This Court cannot substitute its judgment, however valid, for the decision of any agency. Rather this Court must defer to the expertise of the agency, absent a finding that a decision was

arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. KMI has not cleared these hurdles based on the record before the Court. For purposes of clarity, KMI's conduct is considered in two periods of time: (1) between February 2009 and February 2011; and (2) between February 2011 and the present.

1. February 2009 to February 2011

Between February 2009 and February 2011, KMI did not exercise appropriate due diligence to detect and report suspicious orders of controlled substances. *See* 21 C.F.R. § 1301.74(b). KMI's customer files were incomplete and lacking the kind of information required to detect suspicious orders. (*See* Def. Exs. 1026-1032; Cooper Testimony.) The files that were maintained on the pharmacies discussed in the DEA Order were disorganized and should have raised serious concerns of diversion, based on high ratios of cash to insurance sales, high volumes of sales to pain management clinics, high ratios of sales of controlled substances as compared to non-controlled substances, and drug usage reports and doctors' reports reflecting predominant sales of oxycodone. (Cooper Testimony.) Orders were not monitored; pharmacies were not visited; photos were not verified; and suspicious orders were not detected. (*Id*.) While KMI had standard operating procedures on paper (Def. Ex. 1003), it is not clear that these procedures were followed in a routine fashion.

KMI's lack of an effective suspicious order monitoring system is particularly striking in light of the volume of oxycodone that KMI sold to pharmacies in Florida. KMI distributed over 44 million dosage units of oxycodone into Florida in 2010 and early 2011 (Def. Ex. 1007 at 4-5; Wright Testimony). Although KMI did report numerous suspicious customers during 2010 and 2011, KMI did not meet its obligation to detect and report suspicious orders. For example, KMI

failed to sufficiently detect or report orders that varied in size and frequency. (Wright Testimony; Def. Ex. 1007 at 16-26.) KMI's failure to report such orders is particularly troubling given that the prescription drug problem in Florida is well-known throughout the pharmaceutical industry and, in fact, throughout the general public.

Throughout this case, KMI has argued that in implementing certain practices allegedly aimed at curbing the risk of prescription drug diversion, it distinguished between "oxycodone single entity" products – oxycodone without acetaminophen – and "oxycodone combination" products – oxycodone with acetaminophen. This distinction arose when KMI attempted to explain its implementation of "thresholds" and "caps," at various times, on oxycodone sales to Florida. The Court finds, however, that KMI failed to adequately explain the basis for such a distinction. Furthermore, the documentary evidence does not show that KMI ever clearly explained that distinction in its own policy documents or in communications with the DEA. For example, in the November 19, 2010 letter that KMI sent to the DEA (Def. Ex. 1005), in which KMI described changes it planned to make to its Standard Operating Procedures to address concerns regarding the amount of "oxycodone" KMI was selling to its customers in Florida, KMI made no distinction between "oxycodone single entity products" and "oxycodone combination" products.

KMI now argues that it understood DEA's diversion concerns to be focused on "oxycodone single entity" products but not on "oxycodone combination" products. However, there is no credible evidence to support that understanding. None of the DEA witnesses testified that this distinction was part of their understanding of the oxycodone problem. Instead, the DEA witnesses' testimony indicated that all oxycodone products are subject to abuse and that KMI

was required to have an effective suspicious order monitoring system as to all forms of oxycodone. During the period from February 2009 to February 2011, KMI did not have such a system.

2. February 2011 to Present

In February 2011, KMI received the Administrative Inspection Warrant (Def. Ex. 1042), which provided formal notice regarding the DEA's concerns about KMI's practices. At that point in time, KMI had an opportunity to implement a suspicious order monitoring system that would have shown that its continued registration to distribute controlled substances did not pose an imminent danger to the public health and safety.

KMI implemented a number of half-measures that failed to address legitimate concerns regarding its practices. For example, on March 1, 2011, KMI did not stop all oxycodone sales into Florida, but only the sales of "single entity" oxycodone products. (Engel Decl. ¶ 25.) As a result, KMI distributed over one million dosage units of oxycodone combination products into Florida between March 1, 2011 and May 31, 2011. (Wright Testimony; Def. Ex. 1040.) Similarly, KMI representatives admitted that it was a "mistake" to send controlled substances to one customer, Ekeledo Pharmacy, in the early months of 2011. (Engel Testimony; Hoffman Decl. ¶ 23; *see also* Cooper Decl. ¶¶ 8, 9(f).)

This course of conduct is of concern because KMI did not improve significantly its due diligence procedures after the issuance of the Administrative Inspection Warrant. Although KMI hired a compliance officer, he had no experience in the pharmaceutical industry, and KMI gave him no authority to make final compliance decisions. (Testimony of Robert Barnes (July 6, 2011).) In addition, in March 2011, KMI started providing a "single entity" oxycodone product

to a purported hospice/long-term care pharmacy that, at worst, is distributing pills to illegitimate pain clinics, and, at best, failed to provide information to KMI regarding its recent customers – the exact information that KMI's standard operating procedures require for sales of controlled substances to its customers. (*See* Pl. Exs. 66-72; Testimony of Robert Barnes (July 6, 2011).) The due diligence files for that pharmacy were incomplete and contained photos that no one could verify (Pl. Ex. 69) and a hospice contract that was executed five years earlier (Pl. Ex. 72).

Based on the record before this Court, KMI did not demonstrate a substantial likelihood of success on the merits. Specifically, KMI is unlikely to prove that the DEA violated the CSA or the APA in determining that KMI's continued registration posed an imminent danger to the public health or safety. The risk of continued distribution of controlled substances without adequate controls against diversion is imminent harm, as it poses "danger to substance abusers and the public as a whole if [the registrant] were allowed to continue dispensing/diverting large quantities of controlled substances during the pendency of the administrative hearing." *United Prescription Services, Inc. v. Gonzalez*, No. 8:07-cv-316, 2007 WL 1526654, at *4 (M.D. Fla. May 23, 2007) (rejecting claim that recent reforms by registrant eliminated threat of imminent harm).[3]

Similarly, KMI is unlikely to prove that the DEA violated the Fifth Amendment right to due process. "It is well established that the government can, under certain circumstances, seize

[3] *See also Novelty Distributors, Inc.*, 562 F. Supp. 2d 20, 29 (D.D.C. 2008) (refusing to enjoin suspension order and noting that, "[f]or the present purposes, DEA's most significant conclusion relating to these alleged violations is that Novelty failed to maintain effective controls against diversion"); *Easy Returns Worldwide, Inc.*, 266 F.Supp.2d at 1021 (rejecting argument based on recent reforms and noting that "prior violations serve as background to the events which ultimately culminated in the suspension of the registration"); *MediPharm-Rx, Inc. v. Gonzales*, No. 8:06-cv-2223, 2007 WL 601722, at *5 (M.D. Fla. Feb. 16, 2007) (stating that "[t]he prior violations serve as a backdrop to the events that culminated in the DEA's issuance of the Suspension Order.")

property outright without a prior hearing." *First Federal Sav. Bank and Trust v. Ryan*, 927 F.2d 1345, 1358 (6th Cir. 1991). Here, "[t]he DEA has a valid public purpose in halting the alleged diversion of controlled substances." *MediPharm-Rx, Inc. v. Gonzales*, No. 8:06-cv-2223, 2007 WL 601722, at *4-6 (M.D. Fla. Feb. 16, 2007) (rejecting due process challenge).[4]

B. Irreparable Injury

KMI also failed to demonstrate irreparable injury if the enforcement of the DEA Order is not enjoined.

> The key word in this consideration is irreparable. Mere injuries, however substantial in terms of money, time and energy necessarily expended in the absence of a stay, are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm.

Sampson v. Murray, 415 U.S. 61, 90 (1974) (internal quotations omitted).

The evidence presented by KMI does not meet this standard. During the week prior to the issuance of the immediate suspension order, 63% of KMI's sales revenues were from non-controlled substances, which are not affected by the DEA Order. (Testimony of Todd Szewc (July 5, 2011); Pl. Ex. 37.) KMI did not provide projections of revenues and losses if the injunction is not issued. (Szewc Testimony.) Partial and speculative harm does not meet the standard necessary for this Court to issue a preliminary injunction. *See, e.g., Michigan Coal of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 152 (6th Cir. 1991) (stating that "speculative or theoretical" harm is insufficient); *Port City Properties v. Union Pacific R. Co.*, 518 F.3d 1186, 1190 (10th Cir. 2008) (affirming denial of preliminary injunction where suspension impacted only "small part" of aggrieved party's business, and where the injunction

[4] The Court does find, however, that Plaintiff was entitled to challenge the propriety of the immediate suspension in this Court pursuant to 21 U.S.C. § 824(d).

would not put the challenging party out of business).

C. Harm to Third Parties or Public Interest

KMI cannot demonstrate that an injunction is necessary to avoid substantial harm to others or to serve the public interest. Although KMI has a private financial interest in continuing to sell controlled substances, it is plainly outweighed by the compelling public interest in preventing the distribution of controlled substances without adequate controls against diversion. The Court is convinced that this diversion has real consequences, whether to the individual who is able to obtain pills to feed an addiction, citizens who are victims of associated street crimes, or family members who lose loved ones to drug overdoses. (Langston Testimony.) In this case, the requested injunctive relief threatens the public interest in preventing the illegal diversion of controlled substances.

IV. CONCLUSION

For the foregoing reasons, the Court **DENIES** Plaintiff's motion for a preliminary injunction. The DEA Order is permitted to stand as it was issued on June 9, 2011.

IT IS SO ORDERED.

s/Susan J. Dlott
Chief Judge Susan J. Dlott
United States District Court